

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
NEWARK VICINAGE

NOT FOR PUBLICATION

JAZZ PHARMACEUTICALS, INC.,
Plaintiff,

v.

ROXANE LABORATORIES, INC.,
Defendant.

Civil No. 10-6108-ES-SCM
Civil No. 12-6761-ES-SCM
Civil No. 12-7459-ES-SCM

**ORDER AND OPINION ON MOTION TO
CONSOLIDATE ACTIONS**

[D.E. 188]

I. INTRODUCTION

This matter comes before the Court on the motion of Plaintiff Jazz Pharmaceuticals, Inc., ("Jazz") to consolidate *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 with *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 12-6761 and *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 12-7459. (See D.E. 188, Jazz's Motion to Consolidate). Defendant Roxane Laboratories, Inc., ("Roxane") opposes the motion. For the reasons set forth below, the Court will grant Plaintiff's motion.

II. BACKGROUND

This is an action for patent infringement arising from Roxane's filing of Abbreviated New Drug Application ("ANDA") No. 202-090 with

the U.S. Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Jazz's drug product XYREM[®] prior to the expiration of various patents owned by Jazz.¹ XYREM[®] is an oral solution containing the active pharmaceutical ingredient sodium oxybate, and is marketed for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy." (See D.E. 188-1, Jazz's Brief in Support of Motion, at *5). Since Jazz filed its initial Complaint in Civil Action No. 10-6108, two other actions have been consolidated with the instant matter: *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 11-660; and *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 11-2523.

All of the patents-in-suit, the '431, '889, '219, '506

1 Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 301, *et seq.* (also known as the "Hatch-Waxman Act"), a generic pharmaceutical manufacturer may seek expedited approval to market a generic version of a previously approved drug by submitting an ANDA to the FDA. See 21 U.S.C. § 355(j). Pursuant to the Hatch-Waxman Act, an ANDA applicant must show that its generic product is the equivalent of the previously approved drug, and for each patent applicable to the previously approved drug the ANDA must include a certification: (1) that such patent has not been filed (a "Paragraph I" certification); (2) that such patent has expired (a "Paragraph II" certification); (3) of the date on which such patent will expire (a "Paragraph III" certification); or (4) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (a "Paragraph IV" certification). See 21 U.S.C. § 355(j)(2)(A)(vii). The submission of an ANDA containing a Paragraph IV certification constitutes a technical act of patent infringement. *Eli Lilly and Company v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

(together, "the '431 patent family"), as well as the '650 patent that Jazz seeks to consolidate in the instant motion, contain claims related to sodium oxybate, and methods of use and administration of pharmaceutical compounds containing sodium oxybate. (See D.E. 188-1, Jazz's Brief in Support of Motion). In seeking consolidation of its lawsuit alleging infringement of the '650 patent with its earlier filed lawsuits, Jazz contends that the '650 patent contains claims that are substantially similar to the patents in the '431 patent family. *Id.* at *5-8. Accordingly, Jazz contends that there exists common issues regarding infringement, and that the "same questions concerning whether Roxane's ANDA product meets the limitations of the '431, '889, '219, and '506 patents also apply to the '650 patent." See *id.* at *8. Likewise, Jazz asserts that Roxane's allegations regarding the alleged invalidity of the claims of the '431 patent family will involve largely the same evidence as Roxane's allegations concerning the '650 patent. *Id.* at *8-9. In light of this alleged overlap regarding infringement and invalidity issues, as well as relevant evidence, Jazz asserts that consolidation is appropriate. *Id.*

In contrast, Roxane contends that consolidation is inappropriate because the claims of the patents within the '431 family are different from those of the '650 patent, and thus consolidation would not streamline pretrial proceedings. (See D.E.

197, Roxane's Brief in Opposition, at *1). For instance, Roxane asserts that even if the inventors named on the face of the '650 patent are the same as those named on the other patents in the '431 family, additional discovery on each of the named inventors of the '650 patent may be necessary in light of issues specific to the '650 patent that were not relevant in earlier depositions. See *id.* at *6.

Furthermore, Roxane asserts that it will suffer prejudice if the two pending actions are consolidated, as doing so will further postpone the launch of its ANDA product. *Id.*

Lastly, Jazz also seeks to consolidate Civil Action No. 12-7459, a recently filed patent action for infringement of U.S. Patent No. 8,324,275 (the "'275 patent"). According to Jazz, the '275 patent was filed on April 13, 2012, and is a "continuation in the chain of the '431 patent family." (See D.E. 188-1, Jazz's Brief in Support of Motion, at *11). Jazz asserts that the claims of the '275 patent are "substantially similar to the claims of the '506 patent already-in-suit," and that issues of law and fact concerning the validity of '275 patent will be duplicative of issues already pending in the current action. *Id.* Roxane has accepted service of the Complaint in the '275 action and has agreed that, at a minimum, the '275 patent action should be consolidated with the '650 patent action. (See D.E. 197, Roxane's Brief in Opposition, at *9).

III. LEGAL STANDARD AND ANALYSIS

Pursuant to Fed. R. Civ. P. 42(a), consolidation may be appropriate when actions “involve a common question of law or fact”. “The purpose of consolidation is to streamline and economize pretrial proceedings so as to avoid duplication of effort, and to prevent conflicting outcomes in cases involving similar legal and factual issues.” *In Re TMI Litig.*, 193 F.3d 613, 724 (3d Cir. 1999) (internal citations omitted). Under Rule 42(a) a District Court has broad discretion in determining whether to consolidate cases, and in making its decision,

the court must balance the risk of prejudice and possible confusion against the risk of inconsistent adjudications of common factual and legal issues, the burden on the parties and witnesses, the length of time required to conclude multiple lawsuits as against a single one, and the relative expense to all concerned of the sing-trial and multiple-trial alternatives.

A.F.I.K. Holding SPRL v. Fass, 216 F.R.D. 567, 570 (D.N.J. 2003) (internal citations omitted). Thus, a court’s decision regarding consolidation is highly contextual, as a district court must consider the particular facts and circumstances of each individual case. See *In Re Cent. European Distrib. Corp.*, 2012 U.S. Dist. LEXIS 160248, at *23 (D.N.J. Nov. 8, 2012) (citing *Wright & Miller* § 2383).

After considering the parties’ submissions and all other relevant factors in this matter, the Court, in its discretion, will

grant Jazz's motion to consolidate. First, the Court notes that the parties in these two actions are identical. Second, many issues pertaining to infringement are shared between the '605 patent and the patents of the '431 patent family, such as pH, microbial resistance, and chemical stability. As Jazz notes in its moving papers, "six of the nine references cited in Roxane's notice letter of its Paragraph IV Certification concerning the alleged invalidity of the '650 patent have already been cited by Roxane in its invalidity contentions in the earlier-filed case." (See D.E. 188-1, Jazz's Brief in Support of Motion, at *8). Accordingly, a finding of infringement or non-infringement regarding the claims of the patents of the '431 patent family would likely be repeated with regard to the '605 patent, and it is likely that there will be considerable overlap between the evidence used in both actions. As such, it is this Court's determination that streamlining the two proceedings by way of consolidation is appropriate at this time.

While some delay in the '650 patent proceedings may result from consolidation, the Court finds that a balance of all relevant considerations favors joining the two actions. The two cases clearly share significant common questions of law and fact. Both cases involve patents for sodium oxybate, and claims to methods of using the pharmaceutical compositions to treat daytime sleepiness. (See D.E. 188-1, Jazz's Brief in Support, at *6). So, the Court finds

that there is substantial overlap among the patents that Roxane is alleged to have infringed, and that consolidation is appropriate.

The Court acknowledges Roxane's argument that there are specific issues and defenses relating to the '650 patent that may be distinguished from those that pertain to the '431 patent family patents, such as the defense of inequitable conduct. (See D.E. 197, Roxane's Brief in Opposition, at *6). However, the Court notes that, with regard to Roxane's inequitable conduct defense, the ultimate success of that defense is likely to hinge upon allegations of prior art that Roxane has alleged in its invalidity defenses against the '431 patent family patents.² See *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1291-92 (Fed. Cir. 2011). Further, while Roxane asserts that it may face prejudice if it were forced to delay the launch of its ANDA due to the threat of patent infringement, the Court notes that the FDA has not yet granted final approval of Roxane's ANDA product. (See D.E. 197, Roxane's Brief

² The court in *Therasense* noted, in discussing the materiality of prior art needed for an inequitable conduct defense, that "the materiality required to establish inequitable conduct is but-for materiality." 649 F.3d at 1291. Thus, prior art is but-for material if "the PTO would not have allowed a claim if it had been aware of the undisclosed reference." *Id.* An exception to the but-for materiality requirement exists in cases of affirmative egregious misconduct, such as the filing of an unmistakably false affidavit. *Id.* at 1292. In such cases, affirmative egregious misconduct is deemed material. *Id.* The Court notes, however, that mere nondisclosure of prior art references to the PTO, or failure to mention prior art references in an affidavit, does not constitute affirmative egregious misconduct. See *id.*

in Opposition, at *7-8). Additionally, even if litigation involving the '431 patent family patents was resolved, litigation related to the '650 patent would nevertheless remain pending. Accordingly, it is this Court's determination that, under the present circumstances, the possible risk of delay and prejudice that may result from consolidation does not outweigh the benefit of joining the two related actions, Civil Action Nos. 10-6108 and 12-6761.

Finally, the Court will consider Jazz's request to also consolidate the '275 patent action. (See D.E. 188-1, Jazz's Brief in Support of Motion, at *11-12). The parties agree that the newly filed '275 patent action should be included in the event that this Court grants Jazz's motion to consolidate, as doing so will minimize any additional delay and streamline the discovery process. (See *id.*; see also D.E. 197, Roxane's Brief in Opposition, at *10). Considering all of the above, and further noting that the '275 patent action appears to share common issues of law and fact with the other actions pending before this Court, the Court will grant the parties' request to consolidate the '275 patent action with Civil Action No. 10-6108.

IV. CONCLUSION

For all of the reasons above, the motion to consolidate is **GRANTED** and Civil Action Nos. 10-6108, 12-6761, and 12-7459 shall be consolidated for all purposes.

IT IS ON THIS 8th day of April, 2012,

ORDERED that Civil Action Nos. 12-6761 and 12-7459 are hereby consolidated with Civil Action No. 10-6108; and it further

ORDERED that the above captioned docket number, Civil Action No. 10-6108-ES-SCM, will be the **LEAD ACTION**.



Steve C. Mannion

Honorable Steve Mannion, U.S.M.J.
United States District Court,
for the District of New Jersey
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